

PHARMACY BOARD[657]

Adopted and Filed

Pursuant to the authority of Iowa Code sections 124.301 and 147.76, the Board of Pharmacy hereby amends Chapter 11, “Drugs in Emergency Medical Services Programs,” Iowa Administrative Code.

The amendments exclude nonmedicated intravenous solutions from the definition of “drug” as that term is used within the chapter and specify that records that are required to be maintained by or within an emergency medical services (EMS) program under this chapter are to be maintained and made available for inspection and copying by the Board, the Board’s representative, or another authorized individual. The amendments provide that the monthly inspection of drug supplies maintained at the primary emergency medical services program site may be inspected by a pharmacist, a pharmacist-intern, a certified pharmacy technician, or the service director if the program is a pharmacy-based service or by the medical director, the service director, or other designated EMS personnel if the program is a medical director-based program. The amendments also clarify the content and format of the required record to be kept following the administration of a controlled substance.

Requests for waiver or variance of the discretionary provisions of these rules will be considered pursuant to 657—Chapter 34.

Notice of Intended Action was published in the June 13, 2012, Iowa Administrative Bulletin as **ARC 0172C**. The Board received no written comments regarding the proposed amendments. The adopted amendments are identical to those published under Notice.

The amendments were approved during the August 29, 2012, meeting of the Board of Pharmacy.

After analysis and review of this rule making, no impact on jobs has been found.

These amendments are intended to implement Iowa Code chapter 147A and sections 124.301 and 155A.13.

These amendments will become effective on November 7, 2012.

The following amendments are adopted.

ITEM 1. Amend rule **657—11.1(124,147A,155A)**, definition of “Drug,” as follows:

“*Drug*” means a substance as defined in Iowa Code section 155A.3(13) but does not include nonmedicated intravenous solutions such as saline.

ITEM 2. Amend subrule 11.4(2) as follows:

11.4(2) Medical director-based programs. Immediately upon discontinuation of services, all controlled substances shall be jointly inventoried by the medical director and the service director or their respective designees. A record of this inventory shall be maintained by the medical director for two years and be available for inspection and copying by the board, ~~or its~~ the board’s representative, or another authorized individual. All drugs and devices that are the property of the medical director shall be immediately returned to the medical director.

ITEM 3. Amend subrule 11.11(1) as follows:

11.11(1) Each service program shall, jointly with the service director and the responsible individual, develop, implement, and adhere to written policies and procedures for the operation and management of the service program with respect to prescription drugs and devices. These policies and procedures shall be available for inspection and copying by the board, ~~or its~~ the board’s representative, or another authorized individual. The policies and procedures shall be periodically reviewed by the responsible individual, the medical director, and the service director. Documentation of the review shall be maintained.

ITEM 4. Amend subrule 11.20(1) as follows:

11.20(1) Pharmacy-based. The pharmacist in charge, the medical director, and the service director shall jointly develop a list of drugs to be maintained for administration by the service program. The pharmacy shall maintain an accurate list of all prescription drugs including controlled substances that the pharmacy maintains at the primary program site and at any program substation.

a. Replenishment. The responsible individual, the service director, or designee may request that replenishment supplies of drugs be maintained at the primary program site provided that the pharmacy has been supplied with administration records justifying the order. Records of the administration of Schedule III, IV, and V controlled substances and noncontrolled prescription drugs provided to and maintained at the pharmacy shall include, at a minimum: the patient's name; the name, strength, dosage form, and quantity of the drug administered; and the date administered. Records of the administration of Schedule II controlled substances provided to and maintained at the pharmacy shall consist of a written prescription including all of the prescription information required pursuant to Iowa Code section 155A.27 or a copy of the patient care record if the patient care record includes the required prescription information. The pharmacist shall approve every drug taken from the pharmacy's dispensing stock prior to the transfer of the drug to the primary program site. Documentation of this verification shall be maintained within the pharmacy records.

b. Inspections. The pharmacist in charge shall ensure the completion of a monthly inspection of all prescription drugs maintained by the pharmacy at the primary program site and any program substation. Inspection shall include the removal of outdated or adulterated drugs. All drugs removed from administration stock shall be returned to the pharmacy. Records of inspection shall be maintained for two years at the pharmacy. The pharmacist in charge may delegate the conduct of the monthly inspection to another pharmacist, a pharmacist-intern, a certified pharmacy technician, or the service director.

ITEM 5. Amend paragraph **11.20(2)“b”** as follows:

b. Inspections. The medical director shall ensure the completion of a monthly inspection of all prescription drugs maintained by the medical director at the primary program site and any program substation. Inspection shall include the removal of outdated or adulterated drugs. Records of inspection shall be maintained for two years at the primary program site or the program substation. The medical director or service director may designate EMS personnel to conduct required inspections.

[Filed 9/10/12, effective 11/7/12]

[Published 10/3/12]

EDITOR'S NOTE: For replacement pages for IAC, see IAC Supplement 10/3/12.